



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,111	01/18/2001	Jonathan A. Fletcher	B0801/7196 ERP/MAT	8258

7590 02/10/2003

Elizabeth R. Plumer  
c/o Wolf, Greenfield & Sacks, P.C.  
Federal Reserve Plaza  
600 Atlantic Avenue  
Boston, MA 02210-2211

EXAMINER

SAKELARIS, SALLY A

ART UNIT PAPER NUMBER

1634

DATE MAILED: 02/10/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/765,111

Applicant(s)

FLETCHER ET AL.

Examiner

Sally A Sakelaris

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11/26/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 33 and 63-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33 and 63-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11 & 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Response to Arguments***

***Election/Restrictions***

Applicant's arguments filed 11/26/02 have been fully considered but they are not persuasive. Applicant's election with traverse of Group XI, claim 33 and addition of new claims 63-66 in paper No. 16 is acknowledged. The traversal is on the ground(s) that the examiner could, without undue burden on his time or searching efforts, search and examine all claims. It is maintained however, that the *Official Gazette* and notices posted on the PTO website have included guidance "to include up to 10 nucleotide sequences per application." The examiner retains his/her discretion in the inclusion of "up to 10 sequences." It is further maintained that the examiner adhered to the PTO policy concerning restriction practice as defined in 35 U.S.C. 121, "if two or more independent and distinct inventions are claimed in one application, the commissioner may require the application to be restricted to one of the inventions." The examiner maintains that the inventions are distinct, each from the other and have been restricted appropriately.

***Priority***

Acknowledgement of the provisional application drawn to this same subject matter has been made. The filing date of the instant claims is deemed to be the filing date of the provisional application 60/177, 109 filed on 01/20/2000.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33 and 63-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 33 and 63-66 are indefinite and vague because the claims do not recite the basic steps of the claimed method in a positive, active fashion (see Ex parte Erlich 3 USPQ2d, 1011 (BPAI 1986). "Analyzing" is a vague term and does not clearly set forth the method steps required to identify a PAX8-PPAR $\gamma$ 1 molecule. The term includes performing a mental step and is not considered to be an active process step. The claims lack any positive process steps. For example, in the instant case, the Applicant could amend Claim 33 to "An assay for detecting the presence of a fused PAX8-PPAR $\gamma$ 1 molecule comprising detecting a PAX8-PPAR $\gamma$ 1 nucleic acid molecule...".

B. Claims 63 and 64 are indefinite and vague because the claims refer to a "PPAR $\gamma$ " molecule while claims 33, 65 and 66 all refer to a "PPAR $\gamma$ 1" molecule. It is not clear how the two molecules relate to one another and further how their detection would vary ie, the nucleic acid probe is able to detect both the "PPAR $\gamma$ " and "PPAR $\gamma$ 1" molecules.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by Sozzi et al.(Cancer Genetics Cytogenetics, 1992).

Sozzi et al. teaches a method of detecting the translocation(2;3)(q12-13;p24-25) in Follicular Thyroid Adenomas. It is an inherent property of the t(2;3)(q12-13;p24-25) that it contains the PAX8- PPAR $\gamma$ 1" fusion nucleic acid. Accordingly, in view of the breadth of the claims, the method of Sozzi et al., is necessarily one which detects a "PAX8-PPAR $\gamma$ 1" nucleic acid fusion.

*Allowable Subject Matter*

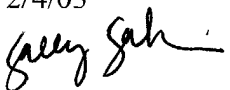
Claims 63-66 are free of prior art. While the closest prior art of Sozzi et al., teaches the translocation(2;3)(q12-13;p24-25) in Follicular Thyroid Adenomas, they do not teach detecting the fused PAX8- PPAR $\gamma$ 1 fusion nucleic acid using a probe which specifically hybridizes to the PAX8- PPAR $\gamma$ 1 junction sequence for the fusion nucleic, nor do they teach detecting the nucleic acid by amplification using individual primers wherein one primer hybridizes to PAX8 nucleic acid and the second primer hybridizes to PPAR $\gamma$ 1 nucleic acid.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Friday from 7:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703)308-1152. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703)605-1237.

2/4/03

  
SALLY SAKELARIS

  
CARLA J. MYERS  
PRIMARY EXAMINER